COVID-19 VACCINE PROVIDER

`WEEKLY NEWSLETTER` 4/16/2021

Highlights

Policy

- Effective 4/13/2021 Pennsylvania Department of Health (DOH) has officially moved to Phase 2 of vaccine rollout, opening universal eligibility to those 16 and older not previously covered and without any contraindication to COVID-19 vaccines.
- Effective 4/14/2021, CDC and FDA recommended a pause in the use of Johnson & Johnson’s Janssen COVID-19 vaccine due to reports of adverse events. ACIP met with federal officials later that day, and did not put forth any formal recommendations. Voting members are waiting for additional data for a more robust risk-benefit analysis on Thursday 4/22 or Friday 4/23.
- Following that recommendation, DOH has enforced a pause on administration of Johnson &Johnson/Janssen vaccine effective April 14 until April 24th, or when CDC and FDA update the guidance.
- For detailed information on Johnson & Johnson vaccine pause, please refer to ‘Johnson &Johnson/ Janssen Vaccine Pause’ section of this newsletter.

Data

- For the week of 4/19 297,520 each of first and second doses of COVID-19 vaccine have been allocated to PA DOH. This allocation data includes Pfizer and Moderna only.
- As of 4/15/2021, a total of 6,736,568 doses have been administered in the jurisdiction of PA DOH. 2,555,581 individuals have been fully vaccinated whereas 4,180,987 individuals have been partially vaccinated against COVID.
- According to the CDC, as of Thursday morning, April 15, Pennsylvania has administered first doses of vaccine to 40.7% of its eligible population, and the state ranks 10th among all 50 states for first doses administered by percentage of population.

Education

FDA’s FAQs on Janssen COVID-19 Vaccine
CDC COVID-19 Vaccine Webinar Series
Best Practice Refresher

Moderna Vaccine Updates

Effective April 1, FDA authorized a Moderna COVID-19 Vaccine EUA to help increase the number of vaccine doses available. Effective same date, FDA also authorized updated storage and handling guidelines for the Moderna vaccine. The highlights of the amendment are as follows:

- Unpunctured vials can be stored Frozen between -50°C to -15°C.
- Now, the unpunctured vials can be stored between 8° to 25°C for up to 24 hrs. Previously, it was 12 hours.
- After a vial has been punctured, it can be stored between 2° to 25°C for up 12 hours. Previously, it was six hours.
- The Moderna COVID-19 vaccine is supplied in two multiple-dose vial presentations:
  - A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
  - A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).

<table>
<thead>
<tr>
<th>Vial</th>
<th>Thaw in Refrigerator</th>
<th>Thaw at Room Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum 11-Dose Vial</td>
<td>Thaw in refrigerated conditions between 2° to 8°C for two hours and 30 minutes.</td>
<td>Alternatively, thaw at room temperature between 15° to 25°C for 1 hour</td>
</tr>
<tr>
<td>(range: 10-11 doses)</td>
<td>Let each vial stand at room temperature for 15 minutes before administering.</td>
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</tr>
<tr>
<td>Maximum 15-Dose Vial</td>
<td>Thaw in refrigerated conditions between 2° to 8°C for three hours. Let each vial</td>
<td>Alternatively, thaw at room temperature between 15° to 25°C for one hour and 30 minutes</td>
</tr>
<tr>
<td>(range: 13-15 doses)</td>
<td>stand at room temperature for 15 minutes before administering.</td>
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</tbody>
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- Please refer to this [updated fact sheet](#) on Moderna for more information.
- Please refer to this [press release](#) from Moderna on updated information on storage and handling instructions.
Johnson & Johnson’s Janssen Vaccine Pause

What happened?

As of April 12, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the U.S. CDC and FDA are reviewing data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine. In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). All six cases occurred among women between the ages of 18 and 48, and symptoms occurred 6 to 13 days after vaccination. Treatment of this specific type of blood clot is different from the treatment that might typically be administered. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this setting, administration of heparin may be dangerous, and alternative treatments need to be given. (Source – CDC, 2021)

What action did CDC take?

CDC’s ACIP held convened an emergency meeting on April 14th that ended without taking a vote to change the current recommendation to pause administration of Janssen vaccine. During the meeting CDC acknowledged that one of the six cases being studied involves 26-year-old PA women who recovered after treatment at a New Jersey hospital. Personal information in this case is not being released by CDC.

What actions did PA DOH take?

PA DOH immediately notified providers on the CDC’s recommendations on 4/14 calling for a pause on Janssen vaccine administration. Operational guidance on Janssen products was emailed to the providers. On April 4/15, providers were updated on the extension of Janssen vaccine’s pause until April 24th or when CDC and FDA update the guidance.

What is the current operation guidance on Janssen vaccine?

- The Department of Health will not be enforcing the order to administer 80% of doses over 7 days for Johnson & Johnson (Janssen) vaccine.
- Continue to store the Janssen vaccine in the refrigerator between 2°C and 8°C (36°F and 46°F).
- Follow vaccine storage practices and continue to monitor and document storage unit temperatures.
- Please continue administering Pfizer and Moderna vaccine to patients as planned.
- Please explain to patients who may have fears that all the vaccines are being constantly monitored for safety and effectiveness, and this announcement shows this process is working.
• If you were planning to administer Johnson & Johnson (Janssen) vaccine to individuals, please cancel those appointments immediately, or if possible, reschedule those appointments using Pfizer or Moderna vaccine.
• It is important that you clearly indicate to patients which vaccine they will be receiving to alleviate any concerns

**Calendar of Upcoming Events**
COVID-19 Vaccine All Provider Network Meeting
Date: April 16th
Time: 12 – 1 pm

COVID-19 Vaccine All Provider Network Meeting
Date: April 23rd
Time: 12 – 1 pm

Note- Link for these meetings are sent to your primary and secondary contact’s email addresses. If you aren’t currently receiving these invitations, please email us at our resource account RA-DHCOVIDVAX@pa.gov

**Helpful Links**

Vaccine Dashboard
Vaccine Finder Map
Personnel Authorized to Administer COVID Vaccine in PA
Provider Resources and FAQs

**Contact Us**
For PA SIIS related inquiries
email: RA-DOHPASIIS@PA.GOV
Phone: 1- 877-774-4748

For all other COVID-19 vaccine related inquiries
email: RA-DHCOVIDVAX@PA.GOV
Phone:1-877-724-32